IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CALLAWAY GOLF COMPANY, Plaintiff, v. ACUSHNET COMPANY, Defendant.	C. A. No. 06-91 (SLR) **PUBLIC VERSION**

DECLARATION OF THOMAS L. HALKOWSKI IN SUPPORT OF PLAINTIFF CALLAWAY GOLF COMPANY'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NO ANTICIPATION

I, Thomas L. Halkowski, declare as follows:

1. I am a principal of Fish & Richardson P.C., counsel of record in this action for plaintiff Callaway Golf Company. I am a member of the Bar of the State of Delaware and am admitted to this Court. I have personal knowledge of the matters stated in this declaration and would testify to them under oath if called upon to do so.

2. Attached as Exhibit 1 is a true and correct copy of U.S. Patent No. 5,383,858.

3. Attached as Exhibit 2 is a true and correct copy of U.S. Patent No. 5,554,389.

4. Attached as Exhibit 3 is a true and correct copy of excerpts from the deposition of Mr. Dennis Nesbitt taken in this matter on April 11, 2007.

5. Attached as Exhibit 4 is a true and correct copy of **REDACTED**

6. Attached as Exhibit 5 is a true and correct copy of excerpts from the deposition of Dr. William J. MacKnight taken in this matter on August 2, 2007.

7. Attached is Exhibit 6 is a true and correct copy of excerpts from the deposition of Dr. Robert J. Statz taken in this matter on August 1, 2007.

Executed this 27th day of August, 2007, at Wilmington, Delaware.

/s/ Thomas L. Halkowski
Thomas L. Halkowski

CERTIFICATE OF SERVICE

I hereby certify that on September 5, 2007, the attached document was electronically filed with the Clerk of Court using CM/ECF which will send electronic notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on September 5, 2007, I have Electronically Mailed the document to the following person(s):

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Thomas L. Halkowski

Exhibit 1

US005383858A

United States Patent [19]

Reilly et al.

[11] Patent Number: 5,383,858

[45] Date of Patent: Jan. 24, 1995

[54] **FRONT-LOADING MEDICAL INJECTOR AND SYRINGE FOR USE THEREWITH**

[75] Inventors: **David M. Reilly**, Glenshaw; **Joseph B. Havrilla**; **Eugene A. Gelblum**, both of Pittsburgh; **Daniel Kazousky**, Trafford, all of Pa.

[73] Assignee: **Medrad, Inc.**, Pittsburgh, Pa.

[21] Appl. No.: **929,926**

[22] Filed: **Aug. 17, 1992**

[51] **Int. Cl.**[6] **A61M 1/00**

[52] **U.S. Cl.** **604/152**; 604/187; 604/131; 604/151

[58] **Field of Search** 604/131, 134, 140, 143, 604/151, 152, 218, 227, 228; 128/655

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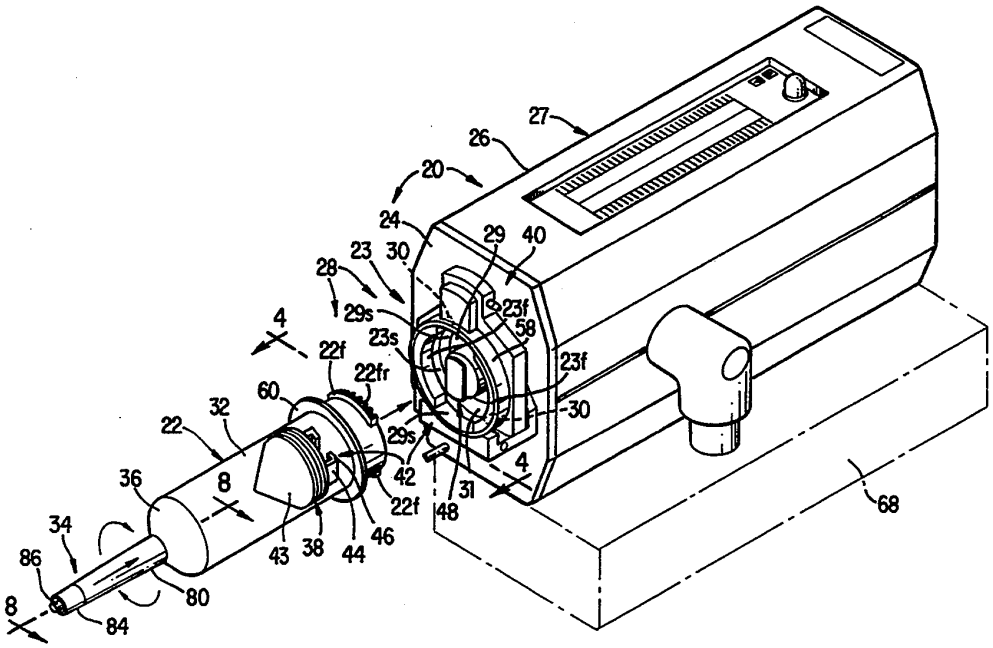
Primary Examiner—John G. Weiss

Attorney, Agent, or Firm—Keck, Mahin & Cate

[57] **ABSTRACT**

A front-loading syringe which comprises a movable plunger for injecting liquid contrast media, is rotatably mountable on a front wall of an injector housing with an interference fit and in sealed relationship with respect thereto, with or without a pressure jacket, by a first-quick release mechanism. At the same time, the plunger is connected to an injector drive mechanism by a second readily releasable mechanism. During the mounting operation, a sensor reads injection information from an indicator device on the syringe and feeds it to an injector control. An audible-and-tactile indicating mechanism also is activated when the syringe is essentially in the desired mounted position. The syringe may include reinforcing ribs which also function as volumetric gradations, and liquid media presence-or-absence indicating dots which appear circular against a liquid media background and oval-shaped against an air background. An injection end of the syringe comprises an injector portion of reduced diameter inside a screw-threaded attachment portion of larger diameter, and may include,loop-shaped reinforcing handle portions.

20 Claims, 5 Drawing Sheets



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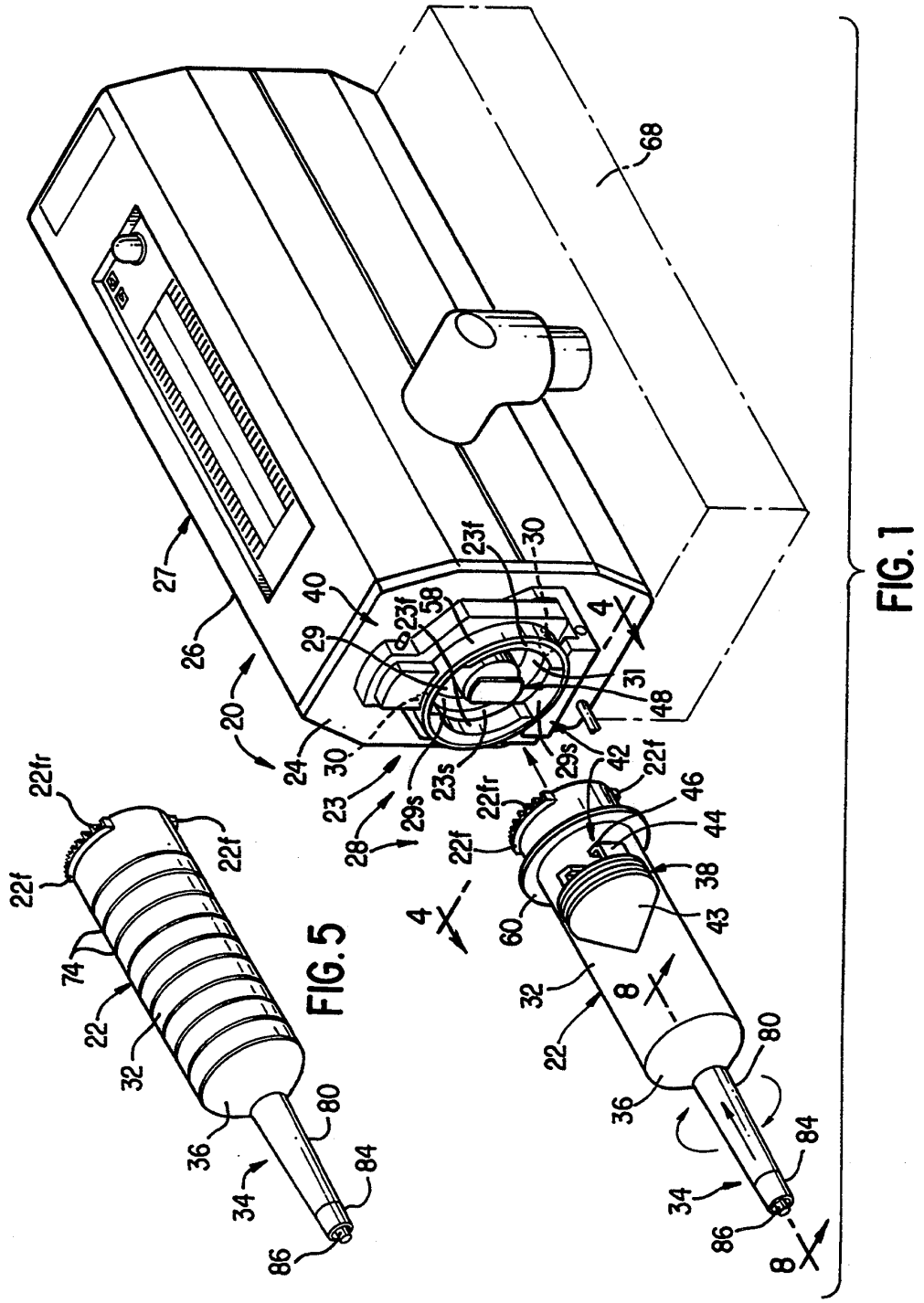


FIG. 1

FIG. 5

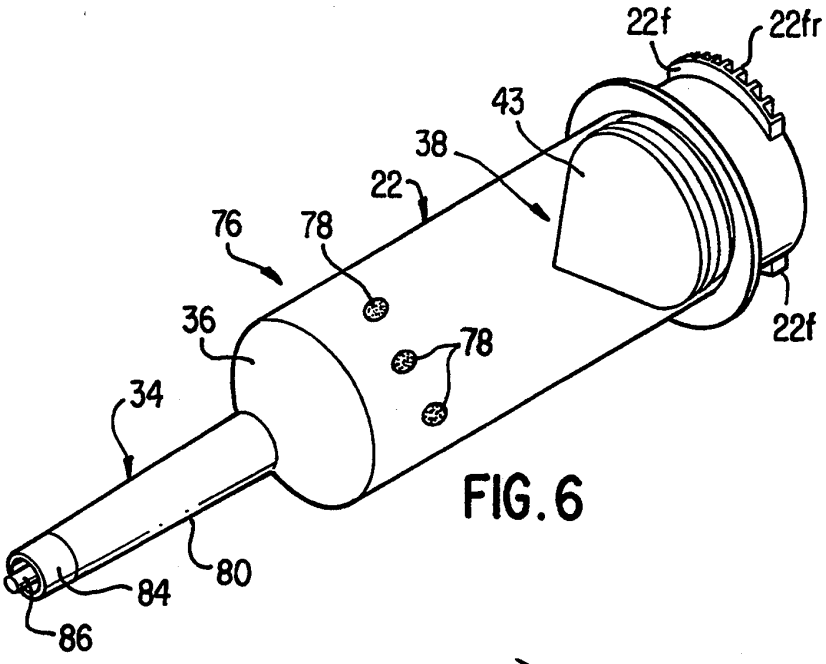

22f
22fr
43
38
22
76
78
36
78
34
22f
80
84
86

FIG. 6

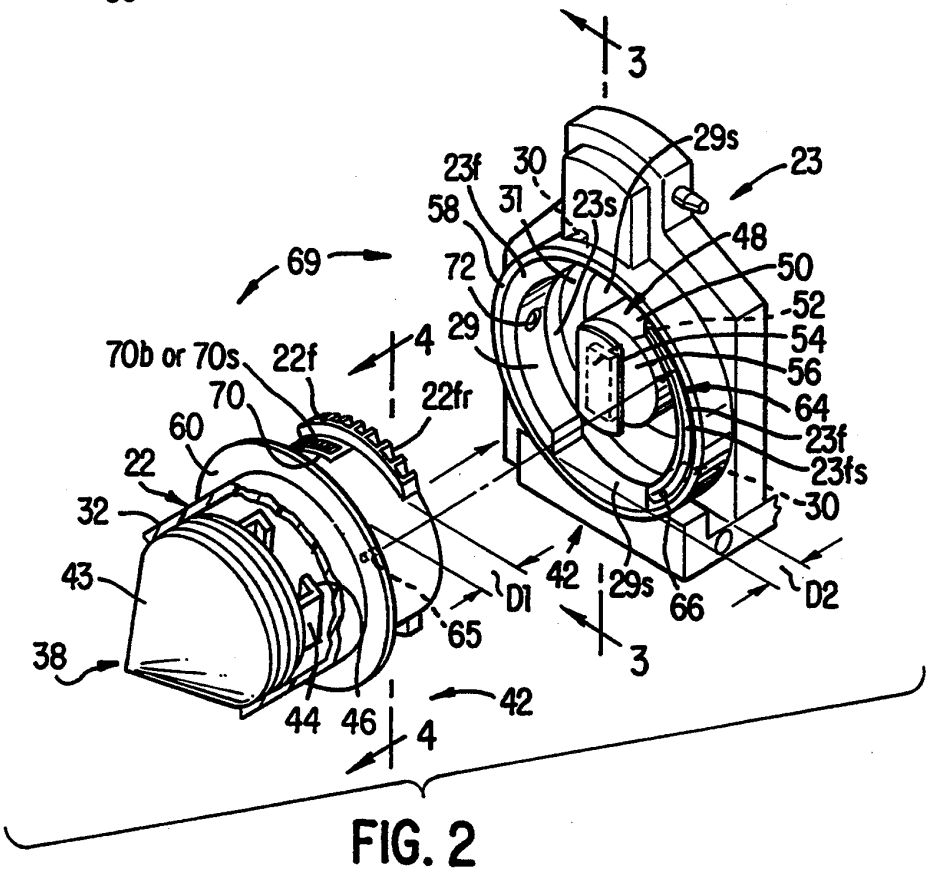

3
29s
23
23f
30
31
23s
58
48
69
72
50
52
29
54
70b or 70s
22f
4
56
70
22fr
64
60
23f
22
23fs
32
30
43
42
29s
66
D2
D1
65
38
3
42
44
46
4

FIG. 2

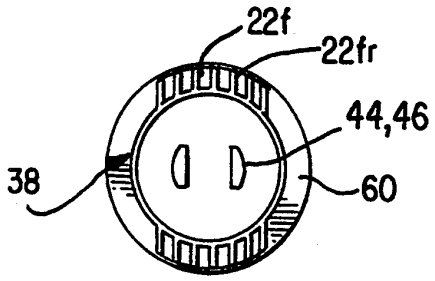

22f
22fr
44,46
38
60

FIG. 4

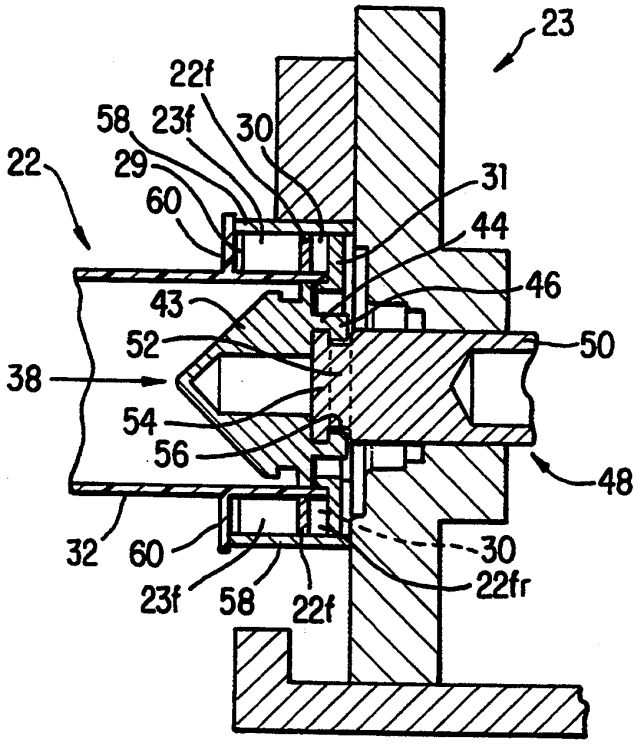

23
22f
58
23f
30
22
29
31
60
44
46
43
52
50
38
54
56
48
32
60
30
22fr
23f
58
22f

FIG. 3

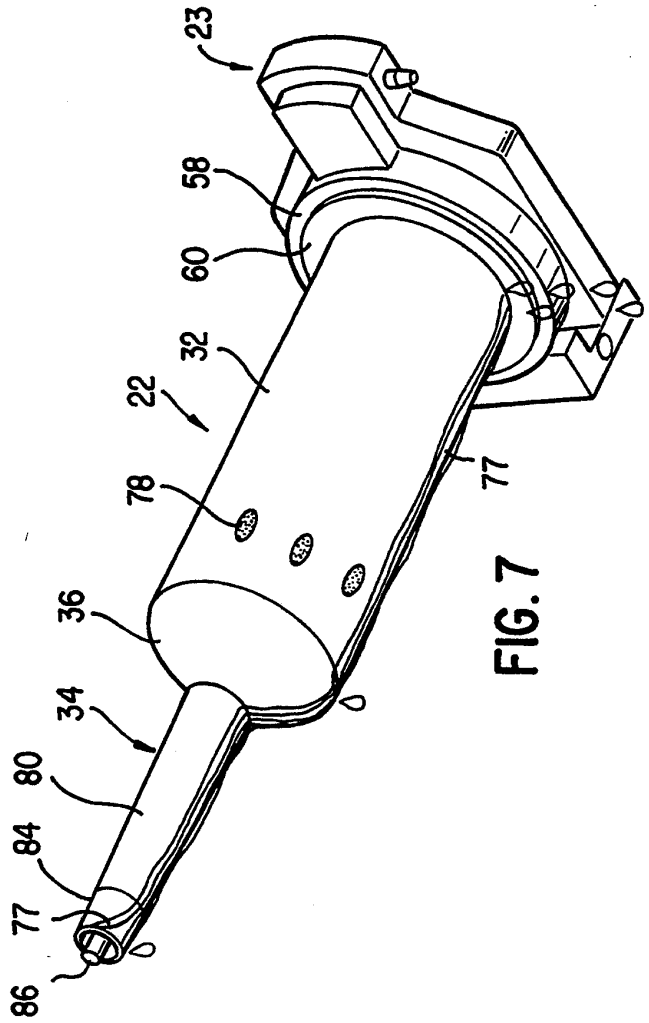


FIG. 7

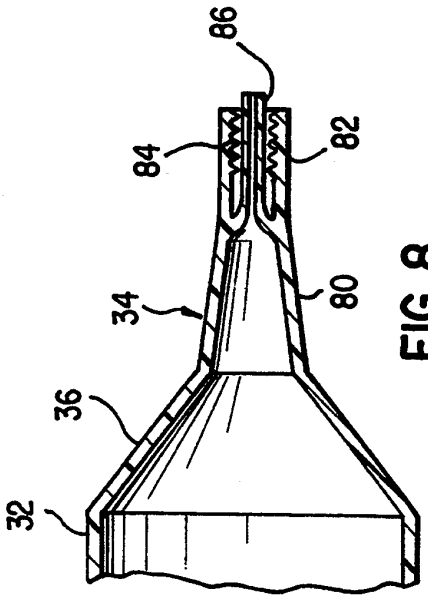


FIG. 8

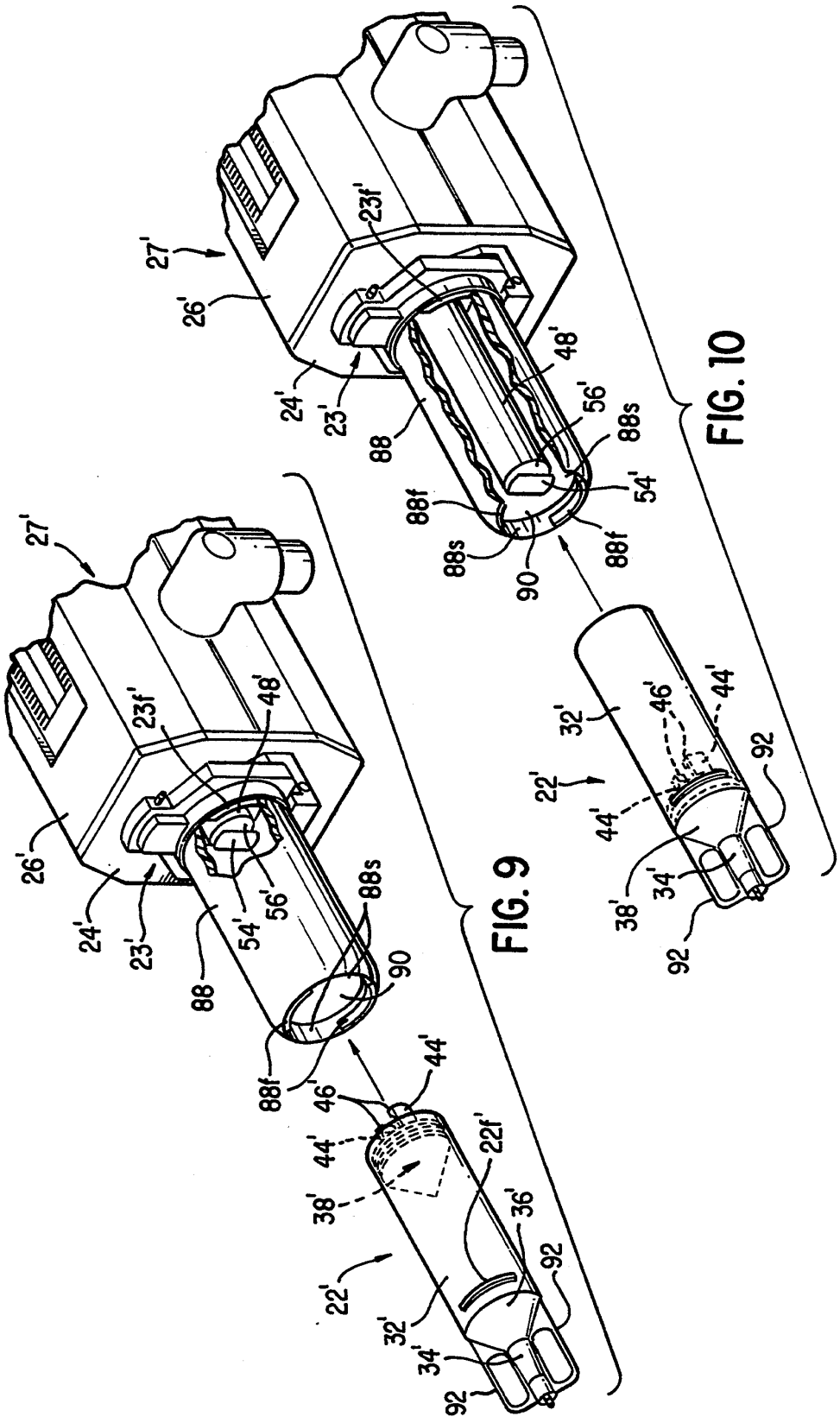


FIG. 9

FIG. 10

FRONT-LOADING MEDICAL INJECTOR AND SYRINGE FOR USE THEREWITH

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a front-loading medical injector and a syringe for use therewith, and more particularly to a front-loading medical injector apparatus wherein a syringe of special construction is mountable upon and removable from a front wall of an injector housing by a first readily releasable mechanism, while a plunger in the syringe is simultaneously connected to or dissembled from an injector drive member by a second readily releasable mechanism.

2. Description of the Prior Art

U.S. Pat. No. 4,006,736, issued to R. J. Kranys et al. on Feb. 8, 1977, and entitled, "Angiographic Injector" which, is assigned to the same Assignee as the subject application, discloses an angiographic injector apparatus for injecting contrast media into the vascular system of an animal, in which angiographic syringes are rear-loaded into a pressure jacket of the injector. More specifically, the apparatus comprises a rotatable turret which carries a pair of the pressure jackets and which is rotatable so that when one of the pressure jackets, into which an angiographic syringe has been rear-loaded, is in an injection position, the other pressure jacket is in a position in which an associated angiographic syringe can be rear-loaded. Subsequently, when injection of contrast media from the first syringe is completed, the turret is rotated to move the first syringe to an unloading-loading position, with the second pressure jacket and the angiographic syringe then being moved into the injection position. In this apparatus, when each of the pressure jackets and its associated syringe has been located in the injection position, a drive member of the injector is moved forward to become drivingly engaged with a plunger in the syringe; however, the manner of engagement between the drive member and plunger is such that the drive member cannot be retracted without also retracting the plunger, which can cause body fluids of the animal to be retracted into the syringe unless the syringe is first disconnected from the animal.

An improved apparatus over the apparatus as disclosed in the Kranys et al. patent, is disclosed in U.S. Pat. No. 4,677,980, issued to D. M. Reilly et al. on Jul. 7, 1987, and entitled "Angiographic Injector and Angiographic Syringe for Use Therewith", which also is assigned to the same Assignee as the subject application. In this apparatus, a drive member of the angiographic injector can be drivingly connected to, or disconnected from, a plunger of an angiographic syringe at any point along the path of travel of the plunger by a readily releasable mechanism. Thus, the apparatus of the Reilly et al. patent represented certain improvements over the Kranys et al. patent. However, the apparatus of the Reilly et al. patent, like that of the Kranys et al. patent, is of a rear-loading type comprising a pair of pressure jackets mounted upon a rotatable turret for moving the pressure jackets and syringes therein between injection and loading positions.

Accordingly, a need exists for a front-loading medical injector and a syringe of special construction so that the syringe can be readily and securely front-loaded directly and accurately in a desired position on the injector, thereby facilitating the loading-unloading operation, and a primary purpose of this invention is to

provide such an arrangement with its various attendant advantages. Further, in certain instances, it is desirable that the syringe not be enclosed in a pressure jacket, in order that an operator be able to view the status of the syringe visually during an injection operation. By allowing the operator to see the syringe, the operator can, e.g., determine whether the syringe is empty or full, determine if it is being filled too fast and/or introducing too many air bubbles, when the syringe is filled, and the amount of contrast that has been delivered or remains in the syringe during a procedure. Another purpose of this invention is, in one embodiment, to provide an injector apparatus of such construction.

SUMMARY OF THE INVENTION

In general, in accordance with the invention, a readily releasable mechanism is provided for supporting a syringe on a front wall of an injector housing for an injection operation. For this purpose, the readily releasable mechanism includes at least one retaining portion on the mounting mechanism releasably engageable with a mating retaining portion on the syringe. Further, an actuating mechanism of the injector includes a drive member which is connectable to a plunger in the syringe for controlling the movement of the plunger in the syringe.

More specifically, the readily releasable mechanism is an interlocking mechanism which is activated and released upon rotation of a rearward portion of the syringe relative to the front wall of the injector housing. At the same time, a second readily releasable interlocking mechanism for connecting the injector drive member to the syringe plunger, and which also is activated and released upon rotation of the syringe relative to the front wall of the housing, interconnects the drive member and the plunger. The first readily releasable mechanism may comprise a mounting mechanism on the front wall of the housing having at least a pair of slots for receiving retaining flanges on the rearward end of the syringe therethrough, with the syringe then being rotated to engage the flanges behind associated retaining flanges of the mounting mechanism. The second readily releasable mechanism comprises respective radially projecting parts on the drive member and the plunger which become drivingly engaged in a similar manner upon rotation of the syringe and the plunger.

The first readily releasable mechanism may be further defined by the mounting mechanism on the injector housing front wall having an annular sealing member against which a resilient annular sealing member on the syringe becomes seated as the syringe is positioned on the mounting mechanism, with the resilient annular sealing member and the retaining flanges on the syringe receiving the retaining flanges on the mounting mechanism therebetween with an interference fit. An audible-and-tactile indicator mechanism, alignment arrows, and/or alignment dots also may be provided to detect when the syringe has been essentially rotated into its desired mounted position against suitable stops, with this mechanism then further functioning to discourage reverse rotation of the syringe on the injector housing. An indicator mechanism for providing liquid media injection information to an injector controller, and a sensor for reading the indicating mechanism, also may be provided on the syringe and the injector housing, respectively. The syringe also may include a mechanism which provides a visual indication of whether the sy-

ringe still includes injection liquid, may have an injector nozzle of reduced diameter surrounded by a screw-threaded cylindrical attachment portion at its injection end (the reduced diameter nozzle serving to minimize the amount of contrast that remains in the syringe after the plunger has been fully extended), may be provided with reinforcing ribs which are longitudinally spaced so as to also function as volumetric gradations, and/or may be formed of relatively strong clear plastic.

In another embodiment of the invention, which utilizes a pressure jacket, the pressure jacket is in the form of an elongated tube having one end mounted on the front wall of the injector housing, and having an opposite open outer end. In a syringe mounting operation, a syringe is inserted into the open end of the tubular jacket until an inner end of the syringe engages against a seat mechanism on the injector housing front wall. During this insertion operation, retaining flanges adjacent the forward end of the syringe pass through slots in the open end of the tubular pressure jacket, whereupon the syringe is rotated to engage the flanges behind corresponding mating retaining flanges at the open end of the jacket. As the syringe is rotated, a plunger in the syringe also rotates into driving engagement with a drive member of the injector. An outer injection end of the syringe also may be provided with reinforcing-handle members.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a partial, isometric view of an injector apparatus in accordance with the invention, showing an injector housing and a syringe in disassembled relationship;

FIG. **2** is an enlarged isometric view of portions of the apparatus shown in FIG. **1**, more specifically illustrating certain features of the invention;

FIG. **3** is a partial, cross-sectional view, taken essentially along the line **3—3** in FIG. **1**, illustrating the injector housing and the syringe in assembled relationship;

FIG. **4** is an end view, as seen essentially along the line **4—4** in FIG. **1**, illustrating features of the syringe;

FIG. **5** is an isometric view of a modified form of the syringe shown in FIG. **1**;

FIG. **6** is an enlarged isometric view of the syringe shown in FIG. **1**, illustrating another feature of the invention;

FIG. **7** is an isometric view of portions of the apparatus shown in FIG. **1** in a different orientation, illustrating a further feature of the invention;

FIG. **8** is a cross-sectional view taken essentially along the line **8—8** in FIG. **1**, illustrating another feature of the invention;

FIG. **9** is an isometric view similar to FIG. **1**, illustrating an embodiment of the invention utilizing a pressure jacket, with an injector drive member and a syringe plunger in a retracted loading position; and

FIG. **10** is an isometric view similar to FIG. **9**, illustrating the apparatus of the pressure jacket embodiment with the injector drive member and the syringe plunger in an advanced loading position.

DESCRIPTION OF THE DISCLOSED EMBODIMENTS

FIG. **1** discloses a injector apparatus **20** of the general type disclosed in the U.S. Pat. Nos. 4,006,736 to R. J. Kranys et al. and 4,677,980 to D. M. Reilly et al., for injecting a liquid contrast media into a vascular system of an animal, but of front-loading construction, rather than rear-loading construction, as disclosed in those patents. Thus, the apparatus of FIG. **1** utilizes a syringe **22** capable of being front-loaded into a mounting assembly **23** on a front wall **24** of a housing **26** of an injector **27** by a first readily releasable mechanism **28**, and also capable of functioning in a injection operation without the use of a pressure jacket, whereas each apparatus of those patents is of a type in which angiographic syringes are rear-loaded into respective pressure jackets supported on a rotatable turret for moving the jackets between injection and loading positions. However, to the extent not inconsistent with this disclosure, the disclosures of those two patents, which both are assigned to Medrad Inc, of Pittsburgh, Pa., the Assignee of the subject application, are hereby incorporated by reference.

With reference to FIGS. **1–3** and the first readily releasable mechanism **28**, the mounting assembly **23** on the front wall **24** of the injector housing **26** is provided with an essentially cylindrical opening **29** for receiving a rearward end of the syringe **22**. The opening **29** includes a pair of upper and lower slots **29***s* (best shown in FIG. **2**) through which respective upper and lower retaining flanges **22***f* of the syringe **22**, having reinforcing ribs **22***fr*, may pass as the rearward end of the syringe is inserted in the opening. The mounting assembly **23** further includes opposed retaining flanges **23***f* on opposite sides thereof so that, after the rearward end of the syringe **22** has been inserted into the opening **29**, and the syringe is rotated clockwise, as viewed in FIG. **1**, the retaining flanges **22***f* on the syringe become engaged behind the retaining flanges **23***f* to secure the syringe to the housing front wall **24**. During this mounting of the syringe **22** on the housing front wall **24**, the rotation of the syringe preferably is limited by suitable rearwardly projecting stops **30** at adjacent ends of the housing front wall retaining flanges **23***f*. The mounting assembly **23** also includes an inner annular ring **31** in spaced relationship to the retaining flanges **23***f*, to provide support for the rearward end of the syringe **22** and also define semi-annular guide slots **23***s* (best shown in FIG. **2**) for receiving the syringe flanges **22***f*.

As is disclosed in the aforementioned D. M. Reilly et al U.S. Pat. No. 4,677,980, and referring again to FIG. **1**, the syringe **22** comprises an elongated main tubular body or barrel **32** and a coaxial discharge injection section **34**, interconnected by an intermediate conical portion **36**. A plunger **38** is slidably positioned within the tubular body **32** and is connectable to an actuating mechanism **40** in the injector housing **26** by a second readily releasable mechanism **42**. The second readily releasable mechanism **42** is formed in part by the plunger **38** comprising a base member **43** having hook or lug members **44** (FIGS. **1**, **3** and **4**) extending rearwardly therefrom, with portions **46** of these members extending radially inward in opposed relationship. The plunger **38** serves to control the ejection of fluid contained within the syringe **22** in a desired quantity and at a desired rate, and the hook members **44** are designed to facilitate axial movement of the plunger in either direction when connected to the actuating mechanism **40** by the second readily releasable mechanism **42**.

Further in this connection, as is best shown in FIGS. **2** and **3**, the actuating mechanism **40**, which reciprocates the plunger **38** in the syringe tubular body **32**, comprises a reciprocable drive member **48** which includes a base portion **50**, a stem **52** (FIG. **3**) and an integral rectangular head **54** extending radially outward

from the stem, all of which form additional parts of the second readily releasable mechanism **42**. The drive member **48**, however, while reciprocable, is not rotatable, as disclosed in the above-mentioned Reilly et al patent. Rather, as the syringe **22** is inserted into the opening **29** in the mounting assembly **23**, the hook members **44** (FIG. **3**) on the plunger **38** initially move past the rectangular head **54** on the drive member **48** on opposite sides thereof into alignment with the stem **52** and slots **56** defined by the rectangular head and the base portion **50**. Then, when the syringe **22** is rotated clockwise to engage the syringe retaining flanges **22***f* behind the retaining flanges **23***f* of the mounting assembly **23**, the radially extending portions **46** of the hook members simultaneously move into the slots **56** to effect a driving engagement between the plunger **38** and the drive member **48** in either a forward or reverse direction, as is best shown in FIG. **3**.

With further reference to FIGS. **1–3**, the mounting assembly **23** further includes a forwardly projecting annular ring or collar **58** which functions to remove extra slack in the mounting slots and assure perpendicular engagement between the plunger **38** and the drive member **48**, as well as for sealing. The retaining flanges **23***f* are mounted within the annular ring **58**. As is illustrated in FIG. **2**, the tubular body **32** of the syringe **22** also includes a resilient annular sealing ring **60** surrounding the tubular body and disposed forward of the syringe retaining flanges **22***f* a preselected distance **D1** essentially equal to a thickness **D2** of the mounting assembly retaining flanges **23***f*. Thus, when the syringe **22** is inserted into the opening **29** in the mounting assembly **23** until the syringe sealing ring **60** engages the annular ring **58**, and is then rotated to engage the syringe retaining flanges **22***f* behind the retaining flanges **23***f*, the latter flanges are received between the syringe retaining flanges and the resilient syringe sealing ring with an interference fit. For this purpose, the retaining flanges **23***f* may be provided with a slight lead-in taper (not shown) to facilitate initial movement thereof between the syringe retaining flanges **22***f* and the resilient sealing ring **60**.

The foregoing mounting arrangement possesses a number of advantages, including minimizing wobble and rotation of the syringe **22** during an injection operation, preventing unwanted rotational disengagement of the syringe from the injector housing **26**, by creating a controlled sliding friction interference fit, preventing contrast media spilled from the injecting end of the syringe, from flowing into the injector housing **26**, as illustrated in FIG. **7**, and eliminating the need for constructing the respective parts to excessively tight tolerances. This tight-fitting mounting of the syringe **22** on the housing front wall **24** is further facilitated by providing the syringe retaining flanges **22***f* with the reinforcing ribs **22***fr* (FIGS. **1**, **2** and **4**) to enhance their structural rigidity. To enhance the sealing capability of the annular rings **58** and **60**, a suitable O-ring (not shown) also may be provided therebetween.

Referring again to FIG. **2**, in the disclosed embodiment of the invention, the resilient annular sealing ring **60** on the syringe **22** and at least one of the retaining flanges **23***f* of the mounting assembly **23** include respective parts which form an audible-and-tactile indicating mechanism **64** for detecting and indicating when the syringe and its plunger **38** have essentially been rotated into a desired mounted position against the stops **30**. More specifically, the retaining flange **23***f* includes an arcuate slot **23***fs* formed in a front surface thereof for receiving a projection **65** on the syringe sealing flange **60** as the syringe is rotated relative to the injector housing front wall **24**. The slot **22***fs* further includes a protuberance **66** spaced slightly from one end of the slot so that this protuberance is engaged by the projection **65** on the syringe sealing ring **60** during rotation of the syringe toward its mounted position, with this engagement providing an audible and tactile feedback indicating that the syringe is essentially in the mounted position. Then, as the syringe **22** continues to be rotated into its mounted position, the projection **65** on the syringe annular sealing ring **60** rides over the protuberance **66** in the slot **22***fs* and into a small space between the protuberance and the end of the slot, just before the retaining flanges **22***f* on the syringe engage their respective stops **30**. The protuberance **66** in the slot **22***fs* then cooperates with the projection **65** to prevent undesired reverse rotation of the syringe **22** out of its mounted position. In the alternative, this arrangement may be reversed, with a slot-protuberance arrangement being provided on the syringe annular sealing ring **60**, and a projection being provided on the one retaining flange **23***f* of the injector housing front wall mounting assembly **23**. Moreover, although this embodiment describes the use of a projection and slot, one should recognize that other means may also accomplish the desired tactile/audible effect. Thus, for example, one may instead use a "dimple" located on the flange **60** which may snap into a receiving hole on the retaining flange **23***f*.

With further reference to FIG. **2**, a system **67** for transmitting syringe information from the syringe **22** to an injector controller **68**, illustrated in phantom lines in FIG. **1**, while attaching the syringe to the injector housing front wall mounting assembly **23**, also is provided. In this instance, the system **67** comprises an encoding device **70**, such as a bar code having spaced bars **70***b* and located on the syringe **22**, and a sensor **72** located on the injector **27**, as for example, in a second one of the connector assembly retaining flanges **23***f*. Then, as the syringe **22** is rotated into its mounted position, the sensor **72** reads the encoding device **70** and forwards associated signals to the injector controller **68**, which then interprets the signals and modifies the function of the injector apparatus **20** accordingly. Examples of the information which could be encoded on the encoding device **70** include dimensions of the syringe **22**, content of the syringe in the case of a pre-filled syringe, manufacturing information such as lot numbers, dates and tool cavity number, recommended contrast media flow rates and pressures, and loading/injection sequences. As an alternative to the encoding device **70** being a bar code with spaced bars **70***b*, the encoding device also could include raised surfaces **70***s* corresponding to the spaced bars, which then would be read by a suitable injector sensor **72** in a similar manner, as the syringe **22** is mounted on the injector housing front wall **24**. In addition to the encoding device **70**, one may also use mechanically readable devices, e.g. a slot, hole, or projection on the syringe **22** or plunger **38** to register against a switch on the mounting assembly **23**, or alternatively an optically readable device, e.g. characters, dots and other geometric shapes, that will send information concerning the type of syringe used to the intelligent circuits of the injector.

Referring to FIG. **5**, since the syringe **22** is being used in this embodiment without a pressure jacket, for strength and visibility of the syringe contents, the sy-

ringe wall may be formed of a clear PET polyester material. In the alternative, the wall of the syringe **22** may be formed of polypropylene reinforced by providing a series of annular ribs **74** on the tubular body **32** of the syringe in longitudinally spaced relationship. Further, by suitably spacing the ribs **74** along the length of the tubular body **32**, such as in equal increments, the ribs also can perform the dual function of serving as volumetric gradations for the purpose of indicating the amount of contrast media in the syringe **22**.

With reference to FIG. **6**, the tubular body **32** of the syringe **22** also may be provided with an indicating mechanism **76** for readily detecting the presence or absence of a liquid contrast media in the syringe. In this instance, the detecting mechanism **76** includes a plurality of integrally molded, textured dots **78** on the syringe **22**, which provide a visual indication of whether the syringe contains liquid or air. More specifically, as illustrated in FIGS. **6** and **7**, when viewed against an air background (FIG. **7**), the dots **78** appear oval-shaped, but when viewed against a liquid contrast media background (FIG. **6**), which has a different index of refraction than air, the dots **78** appear circular.

FIG. **8** illustrates the internal construction of the syringe discharge injection section **34**. Specifically, while a rearward portion **80** of the injection section **34** is of tapered conical construction, a forward connector portion **82** is of generally cylindrical construction and formed with internal screw threads **84** for attaching a catheter (not shown) to the injection section. Further, an injection nozzle **86** of reduced diameter is disposed within the screw-threaded cylindrical connector portion **82** and is integrally molded with the tapered rearward portion **80** of the injection section adjacent the point at which the tapered and cylindrical portions merge together.

FIGS. **9** and **10** disclose an alternate embodiment of the invention in which a front-loading syringe **22'** is mounted on a front wall **24'** of a housing **26'** of an injector **27'** in conjunction with a pressure jacket **88**, preferably formed of a strong clear plastic, such as polycarbonate. The pressure jacket **88** is in the form of an elongated tubular member which is suitably mounted at its rearward end in a mounting assembly **23'** on the housing front wall **24'**, by fitting the flange of pressure jacket **88** into the collar on the mounting assembly **23'**. The pressure jacket **88** also has a forward open end **90** for receiving the syringe **22'**.

Thus, in this embodiment, a pair of opposed inwardly projecting retaining flanges **88*f***, separated by opposed slots **88*s***, are provided adjacent the forward open end of the pressure jacket **88**, rather than in the mounting assembly **23'** on the injector housing front wall **24'** as in the embodiment of FIGS. **1–8**. Similarly, a tubular body **32'** of the syringe **22'** also includes a pair of outwardly projecting retaining flanges **22*f*'** (only one shown) on opposite sides thereof, but in this instance located adjacent the forward end of the tubular body, rather than adjacent its rearward end, as in the embodiment of FIGS. **1–8**. In addition, at the forward end of the syringe **22'**, on opposite sides of a discharge injection section **34'**, a pair of reinforcing, loop-shaped handle portions **92**, for facilitating handling of the syringe, including rotation thereof, are integrally molded with the injection section and a tapered conical intermediate portion **36'**. In other respects, while not specifically disclosed and described, it is to be understood that various other features of the embodiment of the invention disclosed in FIGS. **1–8**, may be incorporated into the embodiment of FIGS. **9** and **10**, as desired.

In use, the syringe **22'** of FIGS. **9** and **10** may be mounted in the pressure jacket **88** with a drive member **48'** of the injector **27'** either in a retracted position, as shown in FIG. **9**, or in an advanced position, as shown in FIG. **10**. For example, with the drive member **48'** in the retracted position, as shown in FIG. **9**, a plunger **38'** is disposed at the rearward end of the syringe **22'**. The syringe **22'** then is inserted into the open end **90** in the forward end of the pressure jacket **88** until the rearward face of the retaining flanges **22*f*'** have engaged against suitable seat members in the pressure jacket **88**, with hook members **44'** of the syringe plunger **38'** having moved beyond a rectangular head **54'** of the drive member **48'** and into alignment with associated slots **56'** in the drive member. At the same time, the retaining flanges **22*f*'** on the syringe **22'** have moved through the slots **88*s*** at the forward end of the pressure jacket **88** into positions rearward of the retaining flanges **88*f*** adjacent the opening **90** in the pressure jacket. The syringe **22'** then is rotated clockwise in FIG. **9**, using the handles **92**, to move radially projecting portions **46'** of the hook members **44'** on the syringe plunger **38'** into the slots **56'** of the drive member **48'**, and to simultaneously move the retaining flanges **22*f*'** on the syringe into engagement behind their respective retaining flanges **88*f*** on the pressure jacket **88**.

In FIG. **10**, in which the injector drive member **48'** is in a forward position, the mounting of the syringe **22'** into the pressure jacket **88** is the same as shown in FIG. **9**, except that the plunger **38'** also is in its forward position in the syringe. In other respects, the mounting of the syringe **22'** on the pressure jacket **88** is essentially the same as previously described for FIG. **9**. However, having the syringe plunger **38'** and the drive member **48'** in their forward positions, as shown in FIG. **10**, has several advantages over the rearward position arrangement of FIG. **9**, from a time standpoint. For example, since the syringe plunger **38'** and the drive member **48'** are already in their forward positions, it is not necessary to move them forward in preparation for a syringe-filling operation; rather, the plunger and the drive member can immediately be retracted for this purpose. Similarly, after an injection operation has been completed, additional time is saved by not having to retract the plunger **38'** and the drive member **48'** in preparation for a next injection operation. Further, this embodiment prevents the drive member **48'** from touching or contaminating the inner wall of syringe **22'**.

In summary, a new and improved system by which an injection syringe, such as the syringe **22** in the embodiment of FIGS. **1–8**, readily can be mounted upon and/or removed from the front wall **24** of the injector housing **26**, has been disclosed. For this purpose, the first readily releasable mechanism **28**, by which the syringe **22** is attached to or removed from the injector housing front wall **26**, and the second readily releasable mechanism **42**, by which the plunger **38** of the syringe is drivingly connected to or released from the drive member **48** of the injector **27** cooperate to produce their respective connections and disconnections simultaneously. Another advantage is that the plunger **38** is capable of being placed in a driven or undriven state at any point along its path, whereby the syringe **22** may be disengaged from the injector **27** without having to retract the drive member, or having to first disconnect the

syringe from an animal being injected before retracting the drive member.

Other desirable features of the invention include the construction of the first readily releasable mechanism **28**, in which the syringe **22** is mounted upon the front wall **24** of the injector housing **26** with an interference friction fit, which is advantageous from the standpoint of minimizing syringe wobble and reverse rotation (disengagement) during an injection operation, and eliminating the need for excessively tight manufacturing tolerances. Proper mounting of the syringe **22** and prevention of disengagement also is facilitated by the audible-and-tactile detecting mechanism **64**. The encoding device **70** on the syringe **22**, in cooperation with the sensor **72** on the injector **27**, also is advantageous from the standpoint of providing "custom programming" of the injector as the syringe is mounted thereon. Elimination of a pressure jacket also is desirable from the standpoint of better visibility of the contents of the syringe **22**, better heat transfer to the syringe contents and decreased cleaning and maintenance otherwise needed due to, e.g., scratching or contamination with contrast media of the pressure jacket.

In order to eliminate the need for a pressure jacket, the syringe **22** also may be made of a relatively strong clear plastic, or may be provided with the annular reinforcing ribs **74**, which also are spaced to function as volumetric gradations, as disclosed in FIG. **5**. Further, the detection of the presence of liquid in the syringe **22** is facilitated by the indicating mechanism **76** in FIG. **6**, in the form of the dots **78** molded into the syringe tubular body **32**, with the dots appearing visually as either oval-shaped or circular, depending upon whether the tubular body contains air or liquid, respectively. In addition to functioning as a part of the first readily releasable mechanism **28** for the syringe **22**, the syringe resilient annular flange **60** also cooperates with the annular ring **58** to create a seal to prevent contrast media spilled from the injection end of the syringe, from flowing into the injector housing **26**, as shown in FIG. **7**. The embodiment of the invention shown in FIGS. **9** and **10** also provides a system by which various other advantages, including time savings in syringe-filling and syringe-changing operations, can be achieved utilizing a pressure jacket, such as the pressure jacket **88** mounted in the connector assembly **23'** on the injector housing front wall **24'**.

While the injector apparatus of the present invention is especially designed for injection, it may be applicable to other systems, angiographic and otherwise. It is therefore understood that the foregoing description and accompanying drawings set forth the preferred embodiments of the invention at the present time. Various modifications, additions and alternative designs will, of course, become apparent to those skilled in the art in light of the foregoing teachings without departing from the spirit and scope of the disclosed invention. Thus, it should be appreciated that the invention is not limited to the disclosed embodiments but may be practiced within the full scope of the appended claims.

What is claimed is:

1. An injector for injecting a liquid from a syringe, said syringe having a plunger, said injector comprising:

a housing having a front wall;

readily releasable mounting means on said housing front wall for supporting the syringe for an injection operation, said readily releasable mounting means including retaining means for releasably engaging a retaining portion on the syringe, slot means of said readily releasable mounting means for receiving therethrough the retaining portion on the syringe, inner surface means of said readily releasable mounting means for engaging the retaining portion on the syringe when the syringe is inserted into and rotated in said readily releasable mounting means;

drive means in said housing movable through said housing front wall for controlling the movement of the plunger in the syringe; and

annular sealing means on the front wall of said housing for engaging annular sealing means on the syringe, for perpendicularly aligning the plunger and the drive means and for minimizing slack between the syringe and the slot means.

2. The injector as recited in claim **1**, wherein said retaining portion on the syringe is a flange having reinforcing ribs.

3. An injector for injecting a liquid from a syringe, the syringe having a plunger, said injector comprising:

a housing having a front wall;

readily releasable mounting means on said housing front wall for supporting the syringe for an injection operation, said readily releasable mounting means including retaining means for releasably engaging a retaining portion of the syringe;

annular sealing means on the front wall of said housing for engaging annular sealing means on the syringe for preventing spilled liquid from a discharge end of the syringe from flowing rearward along the syringe into said injector housing, said retaining means of said readily releasable means being received between the annular sealing means and the retaining portion on the syringe with an interference fit; and

drive means in said housing movable through said housing front wall for controlling the movement of the plunger in the syringe.

4. The injector as recited in claim **3**, wherein the annular sealing means on the syringe is of resilient construction to facilitate said interference fit.

5. An injector for injecting a liquid from a syringe, said syringe having a plunger, said injector comprising:

a housing having a front wall;

readily releasable mounting means on said housing front wall for supporting the syringe for an injection operation, said readily releasable mounting means including retaining means for releasably engaging a retaining portion on the syringe, said readily releasable mounting means being an interlocking mechanism which is activated and released upon rotation of the syringe relative to the front wall of said housing;

annular sealing means on the front wall of said housing for engaging a resilient annular sealing portion of the syringe when the syringe is mounted on said housing; said retaining means of said readily releasable mounting means being received between said annular sealing portion and said retaining portion on said syringe with an interference fit when said syringe is mounted on the front wall of said housing;

audible-and-tactile indicating means for detecting when the syringe has been rotated into a desired mounted position relative to said housing front wall;

sensor means for reading liquid media injection information from an indicator device on the syringe as the syringe is mounted on said housing front wall, and feeding the information to an injector control system; and

drive means in said housing movable through said housing front wall for controlling the movement of the plunger in the syringe.

6. A front-loading syringe for injecting a liquid medium, comprising:

an elongated cylindrical main body of relatively large uniform diameter;

readily releasable mounting means on said cylindrical main body for mounting the syringe in a desired position relative to a front wall of an injector housing, at least one radially projecting retaining flange being located adjacent a forward end of said cylindrical main body, an elongated injection section of a relatively small diameter connected to a forward end of said cylindrical main body; and

a plunger movably mounted in said cylindrical main body for forcing the liquid medium from the syringe through said injection section.

7. A front-loading syringe for injecting a liquid medium, comprising:

an elongated cylindrical main body of relatively large uniform diameter and formed around an axis;

readily releasable mounting means on said cylindrical main body for mounting the syringe in a desired position relative to a front wall of an injector housing, said readily releasable mounting means including at least one radially projecting flange on said cylindrical main body;

an elongated injection section of relatively small diameter connected to a forward end of said cylindrical main body;

a plunger movably mounted in said cylindrical main body for forcing the liquid medium from the syringe through said injection section; and

a circumferentially extending and radially projecting sealing flange on said cylindrical main body spaced in a direction parallel to said axis from said at least one radially projecting retaining flange and cooperable therewith for mounting the syringe on the injector housing with an interference fit.

8. The front-loading syringe as recited in claim 7, wherein said sealing flange is of resilient construction to facilitate said interference fit.

9. A front-loading syringe for injecting a liquid medium, comprising:

an elongated cylindrical main body of relatively large uniform diameter and having a plurality of spaced reinforcing ribs;

readily releasable mounting means on said cylindrical main body for mounting the syringe in a desired position relative to a front wall of an injector housing;

an elongated injection section of relatively small diameter connected to a forward end of said cylindrical main body; and

a plunger movably mounted in said cylindrical main body for forcing the liquid medium from the syringe through said injection section.

10. The front-loading syringe as recited in claim 9, wherein said syringe is formed of clear plastic.

11. The front-loading syringe as recited in claim 9, wherein said reinforcing ribs encircle said cylindrical main body and are longitudinally spaced so as to also function as volumetric gradations.

12. A front-loading syringe for injecting a liquid medium, comprising:

an elongated cylindrical main body of relatively large uniform diameter;

readily releasable mounting means on said cylindrical main body for mounting the syringe in a desired position relative to a front wall of an injector housing;

an elongated injection section of relatively small diameter connected to a forward end of said cylindrical main body;

a plunger movably mounted in said cylindrical main body for forcing the liquid medium from the syringe through said injection section; and

at least one reinforcing-handle portion extending along one side of said injection section.

13. A front-loading syringe for injecting a liquid medium, comprising:

an elongated cylindrical main body of relatively large uniform diameter;

readily releasable mounting means including at least one radially projecting flange on said cylindrical main body for mounting the syringe in a desired position relatively to a front wall of an injector housing;

an elongated injection section of relatively small diameter connected to a forward end of said cylindrical main body;

a plunger movably mounted in said cylindrical main body for forcing the liquid medium from the syringe through said injection section;

second readily releasable means on said plunger for connecting said plunger to a plunger drive member in said injector housing;

a circumferentially extending and radially projecting sealing flange of resilient construction on said cylindrical main body in a preselected spaced relationship from said at least one radially projecting retaining flange and cooperable therewith for mounting the syringe on said injector housing with an interference fit;

audible-and-tactile indicating means on said cylindrical main body for detecting when said syringe has been located in a desired mounted position; and

indicator means on said cylindrical main body for providing liquid media injection information to said injector as said syringe is mounted on said injector.

14. Apparatus for injecting a liquid medium, comprising:

a front-loading syringe for holding the liquid medium and having a plunger;

an injector housing having a front wall;

readily releasable mounting means for supporting said front-loading syringe on said housing front wall for an injection operation;

annular sealing means on the front wall of said housing for engaging annular sealing means on said syringe adjacent a rearward end thereof, for preventing spilled liquid media from a discharge end of said syringe from flowing rearward along said syringe into said injector housing;

a retaining flange of said readily releasable mounting means which is received between said annular sealing means on said syringe and a retaining flange on said syringe with an interference fit; and

drive means movable through said housing front wall for controlling the movement of said plunger in said syringe.

15. Apparatus as recited in claim **14**, wherein said retaining flange has reinforcing fibs.

16. Apparatus as recited in claim **14**, wherein said annular sealing means on said syringe is a flange of resilient construction to facilitate said interference fit.

17. Apparatus as recited in claim **14**, wherein said syringe is formed of clear plastic.

18. Apparatus for injecting a liquid medium, comprising:

a front loading syringe for holding the liquid medium, said syringe including longitudinally spaced reinforcing ribs formed thereon which encircle said syringe so as to also function as volumetric gradations;

an injector housing having a front wall;

readily releasable mounting means for supporting said front loading syringe on said housing front wall for an injection operation; and

drive means movable through said housing front wall for controlling the movement of a plunger in said syringe.

19. Apparatus for injecting a liquid medium, comprising:

a front-loading syringe for holding the liquid medium, said syringe including an elongated injection section, at least one reinforcing-handle portion of said syringe extending along one side of said injection section;

an injector housing having a front wall;

readily releasable mounting means for supporting said front-loading syringe on said housing front wall for an injection operation; and

drive means movable through said housing front wall for controlling the movement of said plunger in said syringe.

20. Apparatus for injecting a liquid medium, comprising:

a front-loading syringe for holding the liquid medium and having a plunger;

an injector housing having a front wall;

readily releasable mounting means for supporting said front-loading syringe on said housing front wall for an injection operation;

drive means movable through said housing front wall for controlling the movement of said plunger in said syringe;

annular sealing means on the front wall of said housing for engaging a resilient annular sealing member on said syringe;

said readily releasable mounting means including a syringe retaining flange on said housing front wall received between a retaining flange on said syringe and said resilient annular sealing member on said syringe with an interference fit;

audible-and-tactile indicating means for detecting when said syringe has been rotated into a desired position on said housing front wall;

means for controlling the operation of the apparatus;

indicator means on said syringe for providing liquid media injection information for the operation of said control means; and

sensor means on said housing front wall for reading said indicator means as said syringe is mounted on said housing front wall, and for feeding the information to said control means.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,383,858
DATED : January 24, 1995
INVENTOR(S) : David M. Reilly et al.

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

Col. 13, line 5, delete the word "fibs" and replace it with --ribs.--

Signed and Sealed this

Eighth Day of August, 1995

Attest:

Attesting Officer

BRUCE LEHMAN

Commissioner of Patents and Trademarks

US005383858B1

REEXAMINATION CERTIFICATE (3044th)

United States Patent [19] [11] **B1 5,383,858**

Reilly et al. [45] Certificate Issued **Oct. 29, 1996**

[54] **FRONT-LOADING MEDICAL INJECTOR AND SYRINGE FOR USE THEREWITH**

[75] Inventors: **David M. Reilly**, Glenshaw; **Joseph B. Havrilla**; **Eugene A. Gelblum**, both of Pittsburgh; **Daniel Kazousky**, Trafford, all of Pa.

[73] Assignee: **Medrad, Inc.**, Pittsburgh, Pa.

Reexamination Request:
No. 90/003,860, Jun. 13, 1995

Reexamination Certificate for:
Patent No.: **5,383,858**
Issued: **Jan. 24, 1995**
Appl. No.: **929,926**
Filed: **Aug. 17, 1992**

Certificate of Correction issued Aug. 8, 1995.

[51] **Int. Cl.**[6] **A61M 1/00**
[52] **U.S. Cl.** **604/152**; 604/187; 604/131; 604/151
[58] **Field of Search** 604/131, 134, 604/140, 143, 151, 152, 228, 227; 128/655

[56] **References Cited**

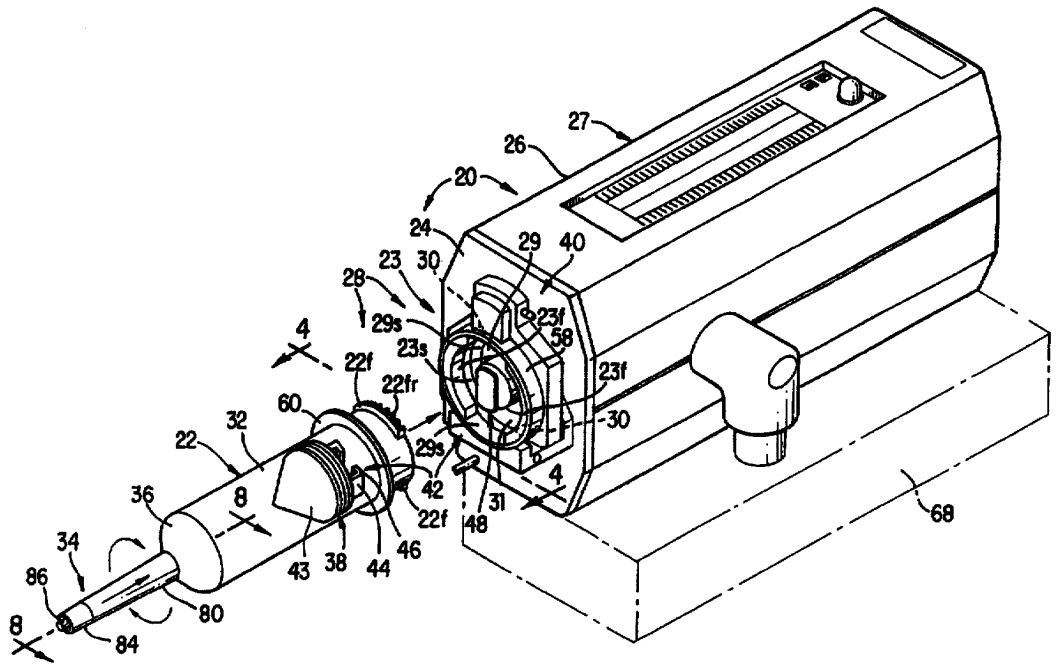
U.S. PATENT DOCUMENTS

5,300,031 4/1994 Neer et al. 604/154

Primary Examiner—John G. Weiss

[57] **ABSTRACT**

A front-loading syringe which comprises a movable plunger for injecting liquid contrast media, is rotatably mountable on a front wall of an injector housing with an interference fit and in sealed relationship with respect thereto, with or without a pressure jacket, by a first-quick release mechanism. At the same time, the plunger is connected to an injector drive mechanism by a second readily releasable mechanism. During the mounting operation, a sensor reads injection information from an indicator device on the syringe and feeds it to an injector control. An audible-and-tactile indicating mechanism also is activated when the syringe is essentially in the desired mounted position. The syringe may include reinforcing ribs which also function as volumetric gradations, and liquid media presence-or-absence indicating dots which appear circular against a liquid media background and oval-shaped against an air background. An injection end of the syringe comprises an injector portion of reduced diameter inside a screw-threaded attachment portion of larger diameter, and may include,loop-shaped reinforcing handle portions.



REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims **1–5** and **7–20** is confirmed.
Claim **6** is cancelled.

* * * * *

Exhibit 2

US005554389A

United States Patent [19]

Badylak et al.

[11] **Patent Number: 5,554,389**

[45] **Date of Patent: Sep. 10, 1996**

[54] **URINARY BLADDER SUBMUCOSA DERIVED TISSUE GRAFT**

[75] Inventors: **Stephen F. Badylak**, W. Lafayette; **Sherry L. Voytik**, Lafayette; **Andrew Brightman**, W. Lafayette; **Matt Waninger**, Frankfort, all of Ind.

[73] Assignee: **Purdue Research Foundation**, West Lafayette, Ind.

[21] Appl. No.: **418,763**

[22] Filed: **Apr. 7, 1995**

[51] **Int. Cl.**[6] **A61K 35/22**

[52] **U.S. Cl.** **424/558**; 424/572; 623/1; 623/11; 623/12; 623/13; 623/14; 623/16; 623/18; 623/19; 623/20; 623/21

[58] **Field of Search** 424/558, 572; 623/1, 11, 12, 13, 14, 16, 18, 19, 20, 21

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Primary Examiner—John W. Rollins
Assistant Examiner—Jean C. Witz
Attorney, Agent, or Firm—Barnes & Thornburg

[57] **ABSTRACT**

A tissue graft composition comprising bladder submucosal tissue delaminated from abluminal muscle layers and at least the luminal portion of the tunica mucosa of a segment of vertebrate urinary bladder is described. The graft composition can be implanted to replace or support damaged or diseased tissues.

10 Claims, No Drawings

URINARY BLADDER SUBMUCOSA DERIVED TISSUE GRAFT

FIELD OF THE INVENTION

The present invention relates to a tissue graft composition and methods for its preparation and use. More particularly, the present invention is directed to non-immunogenic tissue graft compositions comprising urinary bladder submucosa and use of same to promote endogenous tissue growth.

BACKGROUND AND SUMMARY OF THE INVENTION

It is known that compositions comprising the tunica submucosa of the intestine of warm-blooded vertebrates can be used advantageously as tissue graft materials. See U.S. Pat. Nos. 4,902,508 and 5,281,422. The tissue graft compositions described in those patents are characterized by excellent mechanical properties, including high compliance, a high burst pressure point, and an effective porosity index which allows such compositions to be used beneficially for vascular graft and connective tissue graft constructs. When used in such applications the graft constructs appear not only to serve as a matrix for the regrowth of the tissues replaced by the graft constructs, but, indeed, to promote or induce such regrowth of endogenous tissue. Common events to this remodeling process include: widespread and very rapid neovascularization, proliferation of granulation mesenchymal cells, biodegradation/resorption of implanted intestinal submucosal tissue material, and lack of immune rejection.

It is also known that intestinal submucosa can be fluidized by comminuting and/or protease digestion, without loss of its apparent biotropic properties, for use in less invasive methods of administration (e.g., by injection or topical application) to host tissues in need of repair. See U.S. Pat. No. 5,275,826.

There has been much additional research effort directed to finding other natural and synthetic materials having the requisite properties for use as tissue grafts. Surprisingly, it has been found that urinary bladder submucosa (UBS) prepared by delamination of bladder tissue of warm-blooded vertebrates exhibits mechanical and biotropic properties similar to that which has been reported for intestinal submucosal tissue. It can be substituted for intestinal submucosa tissue in most, if not all, of the applications previously reported for intestinal submucosa.

The tissue graft composition of the present invention comprises urinary bladder submucosa derived from urinary bladder tissue of a warm-blooded vertebrate. The wall of the urinary bladder is composed of the following layers: the tunica mucosa (including a transitional epithelium layer and the tunica propria), a submucosa layer, up to three layers of muscle and the adventitia (a loose connective tissue layer)—listed in thickness crossection from luminal to abluminal sides. Urinary bladder submucosa for use in accordance with the present invention is delaminated from the abluminal muscle layers and at least the luminal portion of the tunica mucosa of the urinary bladder tissue. The present graft composition can be implanted or injected into a vertebrate host to induce the repair or replacement of damaged or defective tissues.

DETAILED DESCRIPTION OF THE INVENTION

The tissue graft composition in accordance with the present invention comprises urinary bladder submucosa of a warm-blooded vertebrate delaminated from adjacent bladder

tissue layers. The present tissue graft composition thus comprises the bladder submucosa delaminated from abluminal muscle cell layers and at least the luminal portion of the mucosal layer of a segment of urinary bladder of a warm-blooded vertebrate. Typically the delamination technique described below provides a tissue composition consisting essentially of urinary bladder submucosa. These compositions are referred to herein generically as urinary bladder submucosa (UBS).

UBS graft material is typically prepared from bladder tissue harvested from animals raised for meat production, including, for example, pigs, cattle and sheep or other warm-blooded vertebrates. Thus, there is an inexpensive commercial source of urinary bladder tissue for use in preparation of the tissue compositions in accordance with the present invention.

The preparation of UBS from a segment of urinary bladder is similar to the procedure for preparing intestinal submucosa detailed in U.S. Pat. No. 4,902,508, the disclosure of which is expressly incorporated herein by reference. A segment of urinary bladder tissue is first subjected to abrasion using a longitudinal wiping motion to remove both the outer layers (particularly the abluminal smooth muscle layers) and the luminal portions of the tunica mucosa layers—the epithelial layers). The resulting submucosa tissue has a thickness of about 80 micrometers, and consists primarily (greater than 98%) of a cellular, eosinophilic staining (H&E stain) extracellular matrix material. Occasional blood vessels and spindle cells consistent with fibrocytes are scattered randomly throughout the tissue. Typically the UBS is rinsed with saline and optionally stored in a frozen hydrated state until used as described below.

Fluidized UBS can be prepared in a manner similar to the preparation of fluidized intestinal submucosa, as described in U.S. Pat. No. 5,275,826 the disclosure of which is expressly incorporated herein by reference. The UBS is comminuted by tearing, cutting, grinding, shearing and the like. Grinding the UBS in a frozen or freeze-dried state is preferred although good results can be obtained as well by subjecting a suspension of submucosa pieces to treatment in a high speed (high shear) blender and dewatering, if necessary, by centrifuging and decanting excess water. Additionally, the comminuted fluidized tissue can be solubilized by enzymatic digestion of the bladder submucosa with a protease, such as trypsin or pepsin, or other appropriate enzymes for a period of time sufficient to solubilize said tissue and form a substantially homogeneous solution.

The present invention also contemplates the use of powder forms of UBS. In one embodiment a powder form of UBS is prepared by pulverizing urinary bladder submucosa tissue under liquid nitrogen to produce particles ranging in size from 0.1 to 1mm^2. The particulate composition is then lyophilized overnight and sterilized to form a solid substantially anhydrous particulate composite. Alternatively, a powder form of UBS can be formed from fluidized UBS by drying the suspensions or solutions of comminuted UBS.

The UBS tissue compositions of the present invention lend themselves to a wide variety of surgical applications relating to the repair or replacement of damaged tissues, including, for example the repair of vascular and connective tissues. Connective tissues for the purposes of the present invention includes bone, cartilage, muscle, tendons, ligaments, and fibrous tissue including the dermal layer of skin.

In accordance with the present invention, the graft compositions of the present invention are used advantageously to induce the formation of endogenous tissue at a desired site

in a warm blooded vertebrate. Compositions comprising urinary bladder submucosa can be administered to a vertebrate host in an amount effective to induce endogenous tissue growth at a site in the host in need of same due to the presence of damaged or diseased tissue. The UBS compositions can be administered to the host in either solid or sheet form, by surgical implantation, or in fluidized form, by injection.

In one embodiment the present UBS compositions in sheet form can be used to form vascular grafts. The diameter of the graft should be about the same as the diameter of the recipient blood vessel. This is accomplished by manipulating the UBS to define a cylinder having diameter approximately the same as that of the recipient blood vessel and suturing or otherwise securing the tissue graft longitudinally to form said vascular graft. Thus, for example, a vascular graft can be prepared by selecting a sterile glass rod having an outer diameter equal to that of the recipient blood vessel, wrapping the UBS sheet around the glass rod and gathering the redundant tissue. The desired lumen diameter is achieved by suturing along the length of the graft (for example, using two continuous suture lines or a simple interrupted suture line) or by using other art-recognized tissue securing techniques. The vascular graft is surgically substituted for a damaged or diseased blood vessel using standard vascular surgery techniques.

Consistent with the use of UBS as a vascular graft material, UBS possesses mechanical properties highly desirable for such tissue graft materials, including low porosity index, high compliance, and a high burst pressure point. Those skilled in the art will appreciate that vascular graft material must be of low enough porosity to prevent intraoperative hemorrhage and yet of high enough porosity to allow extension of a newly-developed vasa vasorum through the graft material to nourish the luminal surface. Porosity of a graft material is typically measured in terms of ml of water passed per cm^2min^{-1} at a pressure of 120 mm Hg. UBS has a differential porosity to deionized water at 120 mm Hg pressure. The "porosity index" for UBS from the luminal toward abluminal direction is approximately 6.0; whereas the porosity index in the opposite direction is approximately 50. This property of differential porosity has also been noted for intestinal submucosal tissue but the values are an order of magnitude less than those values for UBS.

The UBS segments can also be used in accordance with this invention as a tissue graft construct for use in the repair or replacement of connective tissues using the same procedures described for use of intestinal submucosa in U.S. Pat. No. 5,281,422 and 5,352,463, expressly incorporated herein by reference. The UBS composition can be used in its delaminated natural sheet form or it can be cut longitudinally or laterally to form elongated tissue segments. Such segments or sheets have an intermediate portion, and opposite end portions and opposite lateral portions which can be formed for surgical attachment to existing physiological structures, using surgically acceptable techniques.

The grafts formed and used in accordance with this invention, upon implantation, undergo biological remodelling. They serve as a rapidly vascularized matrix for support and growth of new endogenous connective tissue. When used as a tissue graft material UBS has been found to be trophic for host tissues with which it is attached or otherwise associated in its implanted environment. The graft material has been found to be remodelled (resorbed and replaced with autogenous differentiated tissue) to assume the characterizing features of the tissue(s) with which it is associated at the site of implantation. In tendon and ligament replacement studies the graft appears to develop a surface that is synovialized. Additionally, the boundaries between the graft and endogenous tissue are no longer discernible. Indeed, where a single graft "sees" multiple microenvironments as implanted, it is differentially remodeled along its length. Thus, for example, when used in cruciate ligament replacement experiments, not only does the portion of the graft traversing the joint become vascularized and actually grow to look and function like the original ligament, but the portion of the graft in the femoral and tibial bone tunnels rapidly incorporates into and promotes development of the cortical and cancellous bone in those tunnels.

For tendon and ligament replacement applications, and other connective tissue repair applications UBS graft constructs are typically preconditioned by stretching longitudinally to a length longer than the length of the urinary bladder submucosa from which the graft construct was formed. One method of "pre-conditioning" involves application of a given load to the urinary bladder submucosa for three to five cycles. Each cycle consists of applying a load to the graft material for five seconds, followed by a ten second relaxation phase. Three to five cycles produces a stretch-conditioned graft material with reduced strain. The graft material does not return to its original size; it remains in a "stretched" dimension. For example, a UBS segment can be conditioned by suspending a weight from said segment, for a period of time sufficient to allow about 10 to about 20% or more elongation of the tissue segment. Optionally, the graft material can be preconditioned by stretching in the lateral dimension. The graft material exhibits similar viscoelastic properties in the longitudinal and lateral dimensions.

The graft segment is then formed in a variety of shapes and configurations, for example, to serve as a ligament or tendon replacement or a patch for a broken or severed tendon or ligament. Preferably, the segment is shaped and formed to have a layered or even a multilayered configuration with at least the opposite end portions and/or opposite lateral portions being formed to have multiple layers of the graft material to provide reinforcement for attachment to physiological structures, including bone, tendon, ligament, cartilage and muscle. In a ligament replacement application, opposite ends are attached using standard surgical technique to first and second bones, respectively, the bones typically being articulated as in the case of a knee joint.

The end portions of the UBS material can be formed, manipulated or shaped to be attached, for example, to a bone structure in a manner that will reduce the possibility of graft tearing at the point of attachment. Preferably the material can be folded or partially exerted to provide multiple layers for gripping, for example, with spiked washers or staples.

Alternatively, the UBS material may be folded back on itself to join the end portions to provide a first connective portion to be attached, for example, to a first bone and a bend in the intermediate portion to provide a second connective portion to be attached to a second bone articulated with respect to the first bone. For example, one of the end portions may be adapted to be pulled through a tunnel in, for example, the femur and attached thereto, while the other of the end portions may be adapted to be pulled through a tunnel in the tibia and attached thereto to provide a substitute for the natural cruciate ligament, the segment being adapted to be placed under tension between the tunnels to provide a ligament function, i.e., a tensioning and positioning function provided by a normal ligament.

The present UBS composition may be sterilized using conventional sterilization techniques including tanning with

glutaraldehyde, formaldehyde tanning at acidic pH, ethylene oxide treatment, propylene oxide treatment, gas plasma sterilization, gamma radiation, and peracetic acid sterilization. A sterilization technique which does not significantly weaken the mechanical strength and biotropic properties of the graft is preferably used. For instance, it is believed that strong gamma radiation may cause loss of strength in the graft material. Because one of the most attractive features of these intestinal submucosa grafts is their ability to induce host-remodelling responses, it is desirable not to use a sterilization approach which will detract from that property. Preferred sterilization techniques include exposing the graft to peracetic acid, low dose gamma irradiation and gas plasma sterilization; peracetic acid sterilization being the most preferred method. Typically, after the tissue graft composition has been sterilized, the composition is wrapped in a porous plastic wrap and sterilized again using electron beam or gamma irradiation sterilization techniques.

We claim:

1. A composition comprising urinary bladder submucosa delaminated from both the abluminal muscle layers and at least the luminal portion of the tunica mucosa of a segment of a urinary bladder of a warm blooded vertebrate.

2. The composition of claim **1** wherein the urinary bladder submucosa is fluidized.

3. The composition of claim **1** wherein the urinary bladder submucosa is digested with a protease for a period of time sufficient to solubilize the tissue and provide a substantially homogenous solution.

4. The composition of claim **1**, wherein the urinary bladder submucosa is dried and in powder form.

5. The composition of claim **1** formed into a cylinder having a predetermined luminal diameter and sutured along the length of the cylinder.

6. The composition of claim **1** conditioned for use as a connective tissue substitute by stretching to produce a graft construct longer than the segment of urinary bladder tissue from which it is formed.

7. A non-immunogenic tissue graft composition capable of inducing endogenous connective tissue growth when implanted in warm-blooded vertebrates, said composition comprising urinary bladder submucosa delaminated from both the abluminal muscle layers and at least the luminal portion of the tunica mucosa of a segment of a urinary bladder of a warm-blooded vertebrate.

8. A method for inducing the formation of endogenous connective tissue at a site in need of endogenous tissue growth in a warm blooded vertebrate, said method comprising transplanting a graft composition comprising urinary bladder submucosa in an amount effective to induce endogenous connective tissue growth at the site the composition is administered.

9. The method of claim **8**, wherein the graft composition is fluidized and is administered by injection into the warm-blooded vertebrate.

10. The method of claim **8**, wherein the graft composition is administered by surgically implanting the composition into the warm-blooded vertebrate.

* * * * *

Exhibit 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CALLAWAY GOLF COMPANY,
Plaintiff,

vs.

ACUSHNET COMPANY,
Defendant.

Civil Action
No. 06-91 (SLR)

Hernando, Florida
Wednesday, April 11, 2007
Volume I of II

Videotaped Deposition of
R. DENNIS NESBITT,

The witness, was called for examination by counsel for the Defendant, pursuant to notice, commencing at 9:12 a.m. at the Best Western Citrus Hills Lodge, 350 East Norvell Bryant Highway, Hernando, Florida, before Patty A. Carlson, Certified Realtime Reporter and Notary Public, when were present on behalf of the respective parties:

DIGITAL EVIDENCE GROUP
1111 16th Street, NW Suite 410
Washington, DC 20036
(202) 232-0646

THE WITNESS: Okay.

THE VIDEOGRAPHER: We're going off the record. The time is approximately 10:09 a.m.

(Recess from 10:09 a.m. to 10:22 a.m.)

THE VIDEOGRAPHER: We are back on the record. The time is approximately 10:22 a.m.

BY MR. ROSENTHAL:

Q. Mr. Nesbitt, you mentioned before the Titleist Pinnacle ball -- or the Acushnet Pinnacle ball. Do you know approximately when that came on the market?

MR. DENNING: Object to the form, lacks foundation.

A. I don't recall the exact date. In the '80s I guess.

Q. Early '80s, do you remember?

A. Early '80s I think.

Q. It was a two-piece solid construction ball?

A. That's right.

MR. DENNING: Object to the form, lacks foundation.

Q. Let's continue with your work at Spalding just to finish that train of thought. You decided to take early retirement around 1999; is that right?

A. Correct.

Q. And then became a consultant for Spalding; is

that right?

A. Correct.

Q. Are you still a consultant for Spalding?

A. I'm a consultant for Top-Flite, Callaway.

Q. Okay. And you have not been employed by Spalding or Top-Flite or Callaway since 1999; is that right?

A. Correct.

Q. What have you been working on since 1999?

A. Could you explain that further?

Q. Sure. In your consultancy with Top-Flite, what sorts of things have you worked on with them?

A. I visited the Chicopee plant, the research lab that I worked in. I went there four times a year, four weeks a year, one week every quarter. I worked on all the current projects that research was working on. I helped out Mark Binnete and other people. I couldn't work on my own projects because I was only there a week.

Q. Now, have you been consistently going there for four weeks, one week a quarter, for the last seven or eight years since you became a consultant?

A. It gradually decreased. Initially I worked three days a week with two days off and two months off, January and February; and then it went to two days a week and then one day a week and then once every

quarter.

Q. Is that where it is now?

A. This year it's less. It's the smallest contract I've ever had.

MR. ROSENTHAL: Okay. We'll get into those contracts when we get them from you, Mr. Denning.

MR. DENNING: We checked at the front desk at the break. They're not here yet.

MR. ROSENTHAL: Okay.

MR. DENNING: As soon as we get them --

MR. ROSENTHAL: Wonderful.

MR. DENNING: -- we'll review them and hand them over.

MR. ROSENTHAL: Let me -- Nesbitt Exhibit 1 is just a notice of deposition, which I always like to mark. You need a copy of that? I assume not.

MR. DENNING: I do not.

MR. ROSENTHAL: Let's mark the next exhibit Nesbitt Exhibit 2.

MR. DENNING: I'll give the copy with the exhibit number to the witness?

MR. ROSENTHAL: Yes. I don't know --

THE WITNESS: Okay.

MR. ROSENTHAL: -- do you need me to pass over to you Callaway stuff or can I just pass that right

to the witness?

MR. DENNING: Stuff from this time frame that the witness -- that was in the witness's -- his name on it and his handwriting and stuff like that, you don't need to pass to me. But I appreciate your --

MR. ROSENTHAL: Very good.

BY MR. ROSENTHAL:

Q. Mr. Nesbitt, do you recognize Exhibit 2?

A. Yes. It's my writing.

Q. Okay. And there's a date on it of November 18, '96, and your initials at the bottom?

A. That's right.

Q. You prepared this around that time frame; is that right?

A. I did. I don't remember it, but it's coming back.

Q. Is this one of the documents you looked at yesterday?

A. No.

Q. Do you have any idea why you created this document?

A. I don't.

Q. Can you take a second and just read the document and see if it helps you recall what it was for.

A. That's just a history of the three-piece golf

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CALLAWAY GOLF COMPANY,
Plaintiff,

vs.

Civil Action
No. 06-91 (SLR)

ACUSHNET COMPANY,
Defendant.

Hernando, Florida
Wednesday, April 11, 2007
Volume II of II

Videotaped Deposition of
R. DENNIS NESBITT,

The witness, was called for examination by counsel for the Defendant, pursuant to notice, commencing at 1:38 p.m. at the Best Western Citrus Hills Lodge, 350 East Norvell Bryant Highway, Hernando, Florida, before Patty A. Carlson, Certified Realtime Reporter and Notary Public, when were present on behalf of the respective parties:

DIGITAL EVIDENCE GROUP
1111 16th Street, NW Suite 410
Washington, DC 20036
(202) 232-0646

Q. -- is that correct?
A. Right.
Q. Why did you want to do that?
A. Because as Molitor said, it gives superior properties. It was the best ionomer at that time that gave the highest coefficient.
Q. When you say "coefficient" --
A. Of restitution, COR.
Q. And that's important because it makes the ball go further?
A. Further, yeah.
MR. ROSENTHAL: Objection, leading.
Q. In your 193 patent Mr. Rosenthal earlier referenced you to a paragraph that talked about the Molitor patent. Do you remember that?
A. I remember that.
Q. If somebody read that to themself and said to you, "Oh, you must have been referring to polyurethane as a potential outer cover material," what would you say to that?
A. No way.
MR. ROSENTHAL: Could you just give me a chance to --
THE WITNESS: You can --
MR. ROSENTHAL: I'm going to object to the

question. It calls for speculation and leading.

THE WITNESS: I already answered it, anyway.

Q. What would you say in response that statement?

MR. ROSENTHAL: Same objection.

A. It had nothing to do with polyurethane. I knew what the Molitor ball was. It was the same ball in the test. The, quote, 10-piece golf ball, was a foam Surlyn. That patent was a foam Surlyn patent. He might have thrown other stuff in it, which I didn't know; but it was a foamed ionomer two-piece.

Q. Mr. Rosenthal also talked about consulting fees and the amount that you have been paid since you left the employ of Spalding and have been a consultant for Top-Flite Golf. What did you do in return for that compensation? What have you been doing from '99 to 2006 for the company?

A. I continue doing what I was doing and best known for doing and that was working on experimental golf balls. I got several more patents based upon the work.

As I say, when I retired I worked -- I'm not sure if I worked four days a week and one week off, but I know I worked three days a week with two days off, and I had two months off. The next year it was two days a week that I worked and still had the two months off to

go to St. Pete's Beach. It was down to one day a week. Then after the one day a week, it went to four weeks a year, one week a quarter. And I was in Florida at the time. I flew up four times a year. The one for 2007 is just a very small one. I expect it's going to go down to zero for next year.

Q. So that time was actually time you spent --

A. In Chicopee, that's right.

Q. -- at the Top-Flite facility?

A. At the Top-Flite -- I was like a Spalding Top-Flite employee, but I wasn't. I was independent. I had my own -- what do you call it -- business. I was incorporated; that was the word I was looking for.

Q. In your experience as a golf ball designer over the years, have you found that golf ball design is a predictable employ?

A. Never predictable, no. You don't know until you try.

Q. What do you mean by that?

A. You play around in the lab. You make examples, and you test it and see if it does what you think it's going to do; if it doesn't, then you go back and make modifications.

Q. It seems like looking through the documents you spend a lot of time sending things to the lab, sending

different formulations, different products to the lab and then reviewing the results?

A. Correct.

MR. ROSENTHAL: Objection, leading.

A. Yeah.

Q. Was that an important part of the design process?

MR. ROSENTHAL: Objection, leading.

A. I wouldn't know what the properties were unless I submitted them and got the results. I can't measure myself the COR. It requires a special machine; I don't have one. So I submit it, and they tell me what the results are.

Q. If you know the chemical properties of the materials going into a golf ball, can you tell with certainty how that golf ball is going to perform?

A. Never by the chemicals. The individual chemical components? No, you never know. You have to mix them all up and make a core, make a cover, make a mantle. They all have to go together. You can't tell by the individual chemicals.

Q. We saw some of the testing that the folks in the lab did on this three-piece golf ball of yours. Can you tell me to the best of your recollection what all the various tests there are to be conducted on a golf

Exhibit 4

REDACTED
IN ITS ENTIRETY

Exhibit 5

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CALLAWAY GOLF COMPANY,

Plaintiff,

VS C.A. No. 06-91(SLR)

ACUSHNET COMPANY,

Defendant.

VIDEOTAPED DEPOSITION OF WILLIAM J. MacKNIGHT

Boston, Massachusetts

Thursday, August 2, 2007

Court Reporter:

Loretta Hennessey

RDR, CRR

JOB No. 69926

would be?
A. Again, I don't recall exactly who said what when.
Q. Okay. But it would have been one of those two gentlemen?
A. It could have been Mr. Rosenthal at another occasion. I don't know.
Q. Okay. During the meeting with Mr. Lester and Mr. Dalton, did they pose any problems to you that they specifically asked you to solve?
MR. BRANNON: Objection, vague.
A. We had a general discussion about the procedures, including the mechanical testing, and of course I was involved in using my background and knowledge to decide as to what tests ought to be run and how they should be done.
Q. So it's your testimony that you told Mr. Dalton and Mr. Lester what tests to run and how to do them?
MR. BRANNON: Objection, misstates --
A. No, that is not my testimony.
Q. Okay. Well, that's what I was trying to ask.
You testified you don't remember

whose idea it was to create these golf balls?
A. I remember only that this was a mutual decision that we arrived at after discussion.
Q. A discussion of what?
A. How we would proceed to make some tests which would be relevant to the litigation involved in this case.
Q. Well, at some point during this meeting among you, Mr. Lester and Mr. Dalton, someone had the idea to make these golf balls you describe in your report, right?
A. I'm not sure about that. It could have been a simultaneous decision or a mutual agreement. I don't know -- well, the answer is I don't know. I don't recall.
Q. During the meeting with Mr. Dalton and Mr. Lester, did either of those two gentlemen do more of the talking than the other?
A. That I don't recall.
Q. Was someone in charge of leading the meeting?
A. It was rather informal. I had been contacted by Mr. Lester to set up the meeting.
Q. Were you shown any documents or presentations during this meeting?
A. I don't recall.

Q. Did you bring any documents or presentations with you to the meeting?
A. I don't recall. I don't believe that I did.
Q. You showed up empty-handed?
A. I don't recall that.
Q. You testified you're not sure exactly who came up with the idea to make these golf balls you described, correct?
A. Correct.
Q. Do you recall who came up with the idea of what tests to run on those golf balls?
A. No.
Q. Do you recall who came up with the idea of how to do those tests?
A. No, I don't.
Q. After your meeting with Mr. Lester and Mr. Dalton, what tasks were assigned to you as a result of that meeting?
A. I was assigned the task to direct the preparation and testing of the golf balls which are described in the patents which I have in my declaration, and that's what I did.
Q. Okay. Were you assigned that task by Mr. Lester or Mr. Dalton?
A. I believe that there was an interaction between

Mr. Lester and Mr. Rosenthal, and that they probably made the final decision, but I can't recall exactly which one.

Q. That is Mr. Rosenthal, the lawyer from Howrey?

A. I think so, yes.

Q. Given that you were assigned the task of directing the preparation and testing of these golf balls, what was your plan to complete that task?

A. Well, as it turned out, as noted in Paragraph 7, for example, we did, at my direction, several things. The golf balls were made at the Acushnet Research and Development Center, and they were then tested for flexural modulus and hardness, in some cases flexural modulus, but mainly hardness, at plastics testing.

And I should be careful not to misspeak. Clearly it's difficult to test a golf ball for flexural modulus. What you do is you test the material that goes into the construction.

Q. In Paragraph 7 of your declaration, you refer to these technical personnel at Acushnet's R&D Department?

A. Yes.

Q. Who were those personnel?
A. They were directed by Mr. Dalton. I do not recall or may never have known the names of any others that were associated with it.
Q. That is, these personnel were people who worked for Jeff Dalton?
A. That is my understanding.
Q. These technical personnel who created the golf balls, did you ever meet with any of them about that task?
A. I had a tour of the facilities when you had this meeting with Mr. Lester and Mr. Dalton, and I'm sure that I met some of them then. What specific ones and what specific tasks they performed, I don't know.
Q. The personnel who created these golf balls, you never directly told them to do that, right?
A. I worked through Mr. Dalton.
Q. And were you present when these personnel made these golf balls?
A. No, I was not.
Q. Was Mr. Dalton present when the golf balls were made?
A. I don't know.
Q. So in Paragraph 7 where you said, "At my

direction, technical personnel at Acushnet's Research and Development department created several golf balls," you weren't directing these personnel directly, correct?

A. My role was to agree or decide or suggest the golf balls' compositions, and then have them prepared at Acushnet. So I didn't direct them personally, no, in the sense of being present.

Q. In the next sentence you say, "In particular, I directed the preparation of 12 samples each of nine constructions of golf balls"?

A. Right.

Q. What do you mean there by you "directed the preparation"?

A. Well, again, I asked them to create those golf balls.

Q. Asked who specifically?

A. Mr. Dalton.

Q. And Mr. Dalton in turn turned this request over to his personnel?

A. That I don't know.

Q. Now, Mr. Dalton didn't create the golf balls himself, did he?

A. I don't know.

MR. BRANNON: Calls for speculation.

Q. He might have?
A. Again, I have no way of knowing.
Q. After these golf balls were created, did you have any further discussions with Mr. Dalton?
A. Yes.
Q. Regarding what?
A. Well, regarding the tests themselves, and this took place at a second meeting at the plastics testing facility which were used.
Q. That's the facility known as PTLI?
A. That's correct.
Q. Where is their facility located?
A. Pittsfield, Massachusetts.
Q. After your golf balls were created, did you have any discussion with Mr. Dalton about how they had been created?
A. I don't recall specifically, but I think we did.
Q. What did you do to insure that the balls had been prepared the way you had instructed them to be?
A. I took Mr. Dalton's word for it.
Q. And he said that they had been prepared in the manner that you had directed?
A. Correct.

Q. Did you perform any inspection of the balls after they had been created?
A. Other than visual inspection of the balls, which I did, that was the only thing.
Q. Okay. You looked at the balls?
A. I did.
Q. Did you handle them?
A. I did.
Q. Did these balls have dimples?
A. They did.
Q. Were they painted?
A. Yes, they were.
Q. Where did you conduct your inspection of these balls?
A. At the PTLI facility.
Q. Do you recall the date of that inspection?
A. I don't. But I'm going to say probably sometime in late May.
Q. At the time you inspected the balls that had been created by the Acushnet R&D personnel, how long had it been since those balls had been finished?
A. If I recall correctly, it was a matter of a week or thereabouts.
Q. Where had those balls been kept in the week or

so after their creation and before your inspection of them?

A. My understanding was that they were kept at the Acushnet facility and then transported to PTLI.

Q. Do you have any knowledge of how those balls were kept at the Acushnet facility; that is, under what conditions or where or how?

A. I believe we discussed that, but I don't recall it, so the answer is no, I don't.

Q. In Paragraph 7 of your declaration, you remark that there were nine golf ball constructions that you directed the creation of. Who directed what those nine constructions would be?

A. Well, again, I think we've already been through that. To the best of my knowledge it was a iterative process which involved myself, Mr. Rosenthal, Mr. Lester and Mr. Dalton.

Q. Was there any special significance to selecting the number 12 as the number of samples to be made from each construction?

A. There wasn't a great deal of significance. We wanted something which would be reasonable statistically, and also the number 12 was mentioned in one of the patents, I believe the

Q. That is who had a discussion about it?
A. Well, it was -- well, in all these cases it would have been the technical person, which was Mr. Dalton, and myself.
Q. Okay. And when you and Mr. Dalton discussed whether to use injection molding versus compression molding, I'm sorry, which did you decide upon using eventually?
MR. BRANNON: Objection, vague. Can you specify which cover layer you're talking about so that we can --
MR. SHUMAN: Oh, okay. I didn't realize that clarification was necessary.
Q. Let me ask you, then. Dr. MacKnight, when you had your discussion with Mr. Dalton about whether to use injection molding versus compression molding, was that in relation to any particular part of the test golf balls?
A. It had to do with the covers.
Q. The outer covers or the inner covers?
A. Both.
Q. And what was decided between you and Mr. Dalton about which methods to use for which covers?
A. Well, the general consensus was injection molding was convenient and appropriate and in

fact mentioned quite frequently in some of the patents, and we would go that route.

I had, through my knowledge, been aware that one of the covers, the so-called one involving the polyurethane and the polyneme, which is in the report later on, is in fact in the category of a thermal set, so I thought that it would probably not be possible to use injection molding for that. However, that wasn't entirely true.

Q. Why was that not entirely true?

A. The curing reaction -- when I refer to "curing reaction," I mean what we technically call cross-linking or setting up of the material is rather slow. While it is taking place, the material is still liquid and can flow. In that state, one can injection mold it, and that's what's done.

Q. Let me ask you this, then. In all of the test golf balls that were made, were the outer and inner cover layers of all of those golf balls made by injection molding?

A. I believe so, yes.

Q. And none of the cover, outer or inner cover layers of those balls were made by compression

molding?
A. That is my belief.
Q. Who made the decision to injection mold the outer and inner covers versus compression mold them?
MR. BRANNON: Asked and answered.
A. I would say, again, this was a mutual discussion, and I cannot answer the question further than that because I don't know.
Q. A mutual discussion between you and Mr. Dalton?
A. And Mr. Dalton. So it was between the two of us. Further than that, I can't go.
Q. Besides convenience, was there any other reason to select injection molding versus compression molding of the covers?
A. Well, I had noted that in some of the patents when formulations of golf balls were discussed, injection molding seemed to be a preferred method.
Q. So injection molding of the covers you thought would not be inconsistent with the prior art patents?
A. Correct.
Q. Let's turn back to Paragraph 7 on Page 2 of your declaration. Twelve samples each of nine

Q. So there could have been, but you just don't know?
A. I don't know.
MR. SHUMAN: Okay, Mr. Brannon, I think I'm ready for a break.
MR. BRANNON: That sounds good.
VIDEO OPERATOR: Going off the record. The time is 10:33.
(Video off.)
(Brief recess.)
(Video on.)
VIDEO OPERATOR: We're back on the record. The time is 10:40.
BY MR. SHUMAN:
Q. Dr. MacKnight, after Mr. Dalton and his personnel created these test golf balls, did you ever see any documentation or notebooks that they created during this project?
A. No.
Q. Do you know if any of them created any documentation related to this project?
A. I don't.
Q. Do you know whether they were asked to or asked not to?
A. I don't know.

Q. The personnel who made these golf balls got their instructions from Mr. Dalton who got them from you; is that right?
A. Right.
Q. And by "instructions," I mean the instructions to make certain types of balls rather than how to make them. So let me ask a different question.
The direction that came from you to the people who actually made the balls was what kind of balls to make, correct?
A. Correct.
Q. You did not direct how to make those balls, correct?
A. No.
Q. Were you present when Mr. Dalton relayed your instructions to his personnel?
A. No, I was not.
Q. Do you know how he gave them those instructions?
A. No.
Q. Do you know if he created any documentation memorializing those instructions?
A. No.
Q. Did you create any documents regarding your

instructions to Mr. Dalton?
A. No.
Q. Let's turn to Paragraph 8, Page 3 of your declaration. The first sentence of Paragraph 8 says, "I directed the preparation of two types of golf ball core materials."
Who selected these two types of golf ball core materials to be made?
A. The eternities -- attorneys, excuse me.
Q. Do you know how they made that selection?
A. To some extent, yes.
Q. Can you explain your understanding of that?
A. Yes. The core that we're looking at -- well, let me be more specific. On Page 8 there's a table which discloses a composition of a core, and that was taken from the Sullivan patent which is abbreviated as '293.
Q. Okay. So the table on Page 3 is a core composition described in the Sullivan '293 patent?
A. Yes.
Q. It's not described in the Nesbitt '193 patent, right?
A. That's correct.
Q. Okay. So what do you mean when you say in

Paragraph 8, "The first golf ball core material is based on the disclosure of Nesbitt '193"?

A. As I state further down the page, Sullivan described the core which is set forth in the, the composition of which is set forth in the table as being representative of the Nesbitt '193 patent and as the prior art ball of the Nesbitt '193 patent. That is my understanding of the basis for using that core in that context.

Q. So without the Sullivan patent's description, how would you know what kind of core the Nesbitt '193 patent contemplated?

A. You wouldn't know directly, other than that he just mentions a solid core, which is all he says. He doesn't give a detailed recipe for a particular core.

Q. Do you have any understanding of why Mr. Sullivan in his patents characterized the Nesbitt core the way he did?

A. Actually, I do not. I assume he has some knowledge which I don't, and I took it as read.

Q. Have you ever spoken to Michael Sullivan?

A. Many times.

Q. Have you ever spoken to Dennis Nesbitt?

Exhibit 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CALLAWAY GOLF COMPANY,
Plaintiff,
v. C.A. No. 06-91 (SLR)
ACUSHNET COMPANY,
Defendant.

Wednesday, August 1, 2007

CONTINUED VIDEOTAPED DEPOSITION of Nonparty Expert Witness DR. ROBERT J. STATZ, Volume 2, taken by Plaintiff, pursuant to agreement, held at the offices of Fish & Richardson P.C., 919 North Market Street, Wilmington, Delaware, before Amy E. Sikora, CRR, CSR, RPR, CLR, Certified Realtime Reporter, Certified Shorthand Reporter, Registered Professional Reporter, Certified LiveNote Reporter, and Notary Public within and for the State of New York.

JOB No. 69924

out of urethane. There's nothing magic there. They were made. DuPont sold SURLYN for foams for years and the urethane people sold urethane foams for years.

Q. I think you may have misspoke. You said Molitor '751. You meant '637?

A. Yeah, but I also put down some notes that he neglected to mention '751 again.

Q. Okay. All right. What's your next -- the next paragraph?

A. Okay. I don't understand. I don't remember why I put that note there.

Q. What's that note?

A. Okay. Acushnet's statement to the patent office regarding -- okay. This is -- okay. I remember now. MacKnight addressing the Titleist patents at the Patent Office.

Q. This is the Hebert patent?

A. Yeah. And really I don't really know anything about that. I had nothing to do with that. I've never seen the file case so I don't know anything about that.

Q. So you haven't seen the file

history for Mr. Hebert's '172 patent?

A. No, no, no. Yes. I wasn't -- that's not my job.

Q. Okay. All right. Let's move on to your next error or omission.

A. Okay. "Plaque hardness is not representative or predictive of outer casing layer hardness." That's not true. That which is soft in a plaque is soft in a cover.

Q. Okay.

A. Okay. We get to 138. We skipped a little bit here.

Q. All right.

A. Okay. That a 72 Shore D, C is inherently -- has a Shore D of 64 or less. A 72C, provided the cover thickness is correct, all right. And if we're talking about Shore C, we're talking about plaques, then a 72 is going to be much less than a 64 Shore D hardness.

Q. You base that on what?

MR. ROSENTHAL: Objection. Asked and answered yesterday.

You can answer the question again, if you want to.

A. Well, you can base it on the table. You can base it on Mike Sullivan's data in some of his patents. If you look very carefully, he'll give plaque hardness and then he'll give hardness on a ball, and he'll give C and D mixed together. Go through and look at those, and you'll find that a 72C is definitely less than a 64.

Q. All right. Let's not cover old ground. Let's move on.

A. Okay. Well, I mean, when I did this it wasn't old ground. Okay. Okay. I didn't have any comments for a few pages here. I must have been tired. Not to say that if I were fresh I couldn't find some more comments.

Okay. Criticizes MacKnight's experiments several times. I think one of the things he pointed out was that the inner layer thickness picked by MacKnight to demonstrate the hardness of the outer cover was the wrong thickness, but if you look in Sullivan's patents, when he did the Nesbitt ball as prior art, he picked just about the same thickness of the inner layer. Do you